

Claims

1. Use of a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, paclitaxel in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole% for manufacturing a pharmaceutical composition for administering to a human patient in need thereof at a monthly dose of about 0.25 mg up to about 60 mg of paclitaxel / kg body weight of said patient.
2. The use of claim 1, wherein said monthly dose is about 0.5 mg up to about 30 mg paclitaxel / kg body weight.
3. The use of claim 1 or 2, wherein said monthly dose is about 1.0 mg up to about 15 mg paclitaxel / kg body weight.
4. The use of claim 1 or 2, wherein said monthly dose is about 1 to about 7.5 mg/paclitaxel/kg body weight.
5. The use of claim 1 or 2, wherein said monthly dose is about 20 to about 60 mg/paclitaxel/kg body weight.
6. The use of any one of the claims 1 to 5, wherein administering said cationic liposomal preparation is at least once a time daily.
7. The use of any one of the claims 1 to 6, wherein administering said cationic liposomal preparation is a plurality of times during a month period, each of said times being separated by an interval of between one day and 3 weeks.
8. The use of any one of claims 1-7, wherein administering said cationic liposomal preparation is

- 43 -

- (i) at least 3 times, especially 3-5 times in a first week, followed by an interval of 1-3 weeks without administration, and optionally one or several repeats of this protocol,
- (ii) once in a first week followed by an interval of at least one week, especially 1-3 weeks, without administration, and optionally one or several repeats of this protocol,
- (iii) once in a week for one week or several successive weeks, or
- (iv) a combination of (i), (ii) and/or (iii).

10 9. Use of a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, paclitaxel in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole% for manufacturing a pharmaceutical composition for simultaneous, separate, or sequential combination therapy with a jointly effective dose of at least one further active agent and/or heat and/or radiation and/or cryotherapy.

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10. The use of claim 9, wherein the composition is for simultaneous combination therapy with a jointly effective dose of at least one further active agent.

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11. The use of any one of the claims 1 to 10, wherein said cationic liposomal preparation comprises paclitaxel in an amount of at least about 2 mole% to about 8 mole%.

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12. The use of any one of the claims 1 to 11, wherein said cationic liposomal preparation comprises paclitaxel in an amount of about 2.5 mole% to about 3.5 mole%.

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13. The use of any one of the claims 1 to 17, wherein said cationic liposomal preparation comprises 50:47:3 mole% of DOTAP, DOPC and paclitaxel.

14. The use of any one of the claims 1 to 13, wherein said cationic liposomal preparation comprises substantially no paclitaxel crystals.

5 15. The use of any one of the claims 1 to 14 for treating an angiogenesis-associated condition.

10 16. The use of claim 15 for treating wound healing, cancer, an inflammatory disease or a chronic inflammatory disease such as rheumatoid arthritis, dermatitis, psoriasis or endometriosis.

15 17. Use of a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, an active agent in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole% for manufacturing a pharmaceutical composition for the prevention or treatment of disorders associated with and/or accompanied by the occurrence of drug resistant cells, e.g. for the prevention or treatment of drug-resistant tumors.

20 18. The use of claim 17 as a second or third line treatment, particularly for cancer.

25 19. The use of claim 17 or 18, wherein said cationic liposomal preparation comprises 50:47:3 mole% of DOTAP, DOPC and paclitaxel.

30 20. Use of a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, an active agent in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole% for manufacturing a pharmaceutical composition for the prevention or treatment of metastasis formation, e.g. onset and/or progression, particularly associated with and/or accompanied by a tumor disorder.

21. The use of claim 20 for manufacturing a pharmaceutical composition for the prevention or treatment of liver metastasis formation.
- 5 22. Use of a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, an active agent in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole% for manufacturing a pharmaceutical composition for simultaneous, separate, or sequential combination therapy with a jointly effective dose of at least one further active agent and/or heat and/or radiation and/or cryotherapy against metastasis onset and/or progression, e.g. associated with and/or accompanied by the tumors.
- 10 23. The use of claim 22, wherein the composition is for simultaneous combination therapy with a jointly effective dose of at least one further active agent.
- 15 24. The use of any one of the claims 17 to 23, wherein said active agent is selected from a cytotoxic or cytostatic substance such as an anti-tumor or an anti-endothelial cell active substance, a chemotherapeutic agent or an immunological active substance.
- 20 25. The use of any one of claim 20-24, wherein said cationic liposomal preparation comprises 50:47:3 mole% of DOTAP, DOPC and paclitaxel.
- 25 26. The use of any one of claims 20-25, wherein said active agent is selected from a taxane, a camptothecin, a statin, a depsipeptide, thalidomide, other agents interacting with microtubuli such as discodermolide, laulimalide, isolaulimalide, eleutherobin, Sarcodictyin A and B, and in a most preferred embodiment it is selected from paclitaxel, docetaxel, camptothecin or any derivative thereof.

27. The use of claim 9 or 22, wherein said further active agent is an anti-endothelial cell active substance, an anti-tumor active substance, a chemotherapeutic agent, an immunological active substance, a compound that reduces or eliminates hypersensitivity reactions or a chemosensitizer.
28. The use of claims 9, 22 or 27, wherein said further active agent is selected from antineoplastic agents especially antimitotic agents like paclitaxel, alkylating agents especially platinum containing compounds like cisplatin, carboplatin, DNA topoisomerase inhibiting agents like camptothecin or doxorubicin, RNA / DNA antimetabolites, especially 5-fluorouracil or gemcitabine and other compounds having antitumor activity.
29. The use of claim 27, wherein said compound that reduces or eliminates hypersensitivity reactions is selected from the group comprising steroids, antihistamines, H₂ receptor antagonists, and combinations thereof in a sufficient amount to prevent fatal anaphylactic reactions.
30. The use of claim 28, wherein said compound is selected from the group comprising Ranitidine, Dexamethasone, Diphenhydramine, Famotidine, Hydrocortisone, Clemastine, Cimetidine, Prednisolone, Chlorpheniramine, Chlorphenamine, Dimethindene maleate, and Promethazine.
31. The use of claim 27, wherein said chemosensitzier is selected from the group comprising cell cycle modulators, substances that revert a drug resistance like verapamil, vasoactive substances like anti-hypertensive drugs, substances that modify interactions of cationic liposomes with blood components like protamine.

- 47 -

32. The use of any one of claims 1-31 for the treatment of cancer, especially pancreatic cancer, inoperable pancreatic cancer, gastrointestinal cancer, lung cancer, colorectal or gastric cancer, breast cancer, prostate cancer and melanoma.

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33. The use of any one of the claims 1 to 32, wherein said cationic liposomal preparation comprises liposomes having an average particle diameter from about 25 nm to about 500 nm, preferably about 100 nm to about 300 nm.

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34. The use of any one of the claims 1 to 30, wherein said cationic liposomal preparation is administered systemically, preferably intravenously.

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35. Use of a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, paclitaxel in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole% for manufacturing a pharmaceutical composition for administering to a human patient in need thereof at a monthly dose of about 9 mg up to about 2337 mg of paclitaxel/m² body surface of said human patient.

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